

of this chapter, but may require bioequivalency and safety information.

[40 FR 13838, Mar. 27, 1975, as amended at 47 FR 51564, Nov. 16, 1982; 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.763c Dithiazanine iodide and piperazine citrate suspension.

(a) *Specifications.* Each milliliter of the drug contains 69 milligrams of dithiazanine iodide and 83 milligrams of piperazine base (as piperazine citrate).

(b) *Sponsor.* See 000010 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Amount.* 1 ounce (30 milliliters) per 100 pounds of body weight for the first 500 pounds; ¾ ounce for each 100 pounds thereafter, up to 1,200 pounds; 10¼ ounces to animals over 1,200 pounds.

(2) *Indications for use.* For control of large roundworms, *Parascaris equorum*; small strongyles; large strongyles, *Strongylus vulgaris*; and pinworms, *Oxyuris equi*.

(3) *Limitations.* Administer by drench or mixed with the daily ration as a single dose. Treatment is recommended in spring and fall. In a heavily infested environment, treatment may be repeated every 30 days. Not for use in horses intended for food purposes. Severely debilitated animals should not be wormed except on the advice of a veterinarian. If the drug is for administration by stomach tube, it shall be labeled: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

[47 FR 52696, Nov. 23, 1982, as amended at 48 FR 32342, July 15, 1983; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.784 Doxylamine succinate tablets.

(a) *Specifications.* The drug is in tablet form and contains doxylamine succinate as the active drug ingredient.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.¹

(2) It is administered orally to horses at a dosage level of 1 to 2 milligrams per pound of body weight per day divided into 3 or 4 equal doses. It is administered orally to dogs and cats at a dosage level of 2 to 3 milligrams per pound of body weight per day divided into 3 or 4 equal doses.¹

(3) Not for use in horses intended for food.¹

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 60140, Nov. 25, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.804 Enalapril tablets.

(a) *Specifications.* Each tablet contains either 1.0, 2.5, 5.0, 10.0, or 20.0 milligrams of enalapril maleate.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.5 to 1.0 milligram of enalapril maleate per kilogram of body weight per day.

(ii) *Indications for use.* Treatment of mild, moderate, and severe (modified New York Heart Association Class II, III, IV) heart failure in dogs.

(iii) *Limitations.* Use 0.5 milligram per kilogram once daily. In the absence of adequate clinical response within a 2-week period, use may be increased to twice daily (a total of 1.0 milligram per kilogram). Enalapril maleate is administered as conjunctive therapy with furosemide and digoxin in the treatment of dilated cardiomyopathy and furosemide with or without digoxin in the treatment of chronic valvular disease. The safety of enalapril for use in breeding dogs has not been established. Use in pregnant bitches is not recommended. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter.

(2) [Reserved]

[59 FR 17694, Apr. 14, 1994, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.812 Enrofloxacin tablets.

(a) *Specifications.* Each tablet contains either 5.7, 22.7, or 68.0 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use.* Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations.* Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 3444, Jan. 24, 1989, as amended at 55 FR 43327, Oct. 29, 1990; 62 FR 38906, July 21, 1997]

§ 520.813 Enrofloxacin oral solution.

(a) *Specifications.* Each milliliter of concentrate solution contains 32.3 milligrams of enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.228 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(i) *Chickens and turkeys*—(i) *Amount.* 25 to 50 parts per million of enrofloxacin in drinking water.

(ii) *Indications.* Chickens: Control of mortality associated with *Escherichia coli* susceptible to enrofloxacin. Turkeys: Control of mortality associated with *E. coli* and *Pasteurella multocida* (fowl cholera) susceptible to enrofloxacin.

(iii) *Limitations.* Do not use in laying hens producing eggs for human consumption. Administer medicated water continuously as sole source of drinking water for 3 to 7 days. Prepare fresh stock solution daily. Effects on the reproductive function of turkeys have

not been determined. Treated animals must not be slaughtered for food within 2 days of the last treatment. Individuals with a history of hypersensitivity to quinolones should avoid exposure to this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 56893, Nov. 5, 1996]

§ 520.816 Epsiprantel tablets.

(a) *Specifications.* Each tablet contains either 12.5, 25, 50, or 100 milligrams of epsiprantel.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of canine cestodes *Dipylidium caninum* and *Taenia pisiformis*.

(2) *Cats*—(i) *Amount.* 1.25 milligrams per pound of body weight.

(ii) *Indications for use.* Removal of feline cestodes *D. caninum* and *T. taeniaeformis*.

(3) *Limitations.* For oral use only as a single dose. Do not use in animals less than 7 weeks of age. Safety of use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50615, Dec. 8, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.823 Erythromycin phosphate.

(a) *Specifications.* Erythromycin phosphate is the phosphate salt of the antibiotic substance produced by the growth of *Streptomyces erythreus* or the same antibiotic substance produced by any other means. One gram of erythromycin phosphate is equivalent to 0.89 gram of erythromycin master standard.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.230 of this chapter.

(d) *Conditions of use.* It is used in drinking water as follows:

(1) *Broiler and replacement chickens*—(i) *Amount.* 0.500 gram per gallon.